

Essentially Derived Varieties: Registration under Protection of Plant Varieties and Farmers' Rights Act 2001*

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ABSTRACT The Protection of Plant Varieties and Farmers' Rights Act, 2001 has provision for registration of "essentially derived varieties" (EDV). By definition EDV is a variety developed from a protected "initial variety" (IV), retaining most essential characteristics of IV and incorporating at least one additional distinguishable characteristic. However, the questions related with genetic similarity between EDV and IV, thereby its dependency on IV for essential characteristics, act of derivation and distinctiveness for additional trait(s) are still being debated for identification criteria/methods and threshold levels to be used for their assessment. In addition, registration of EDV is linked with authorisation from the breeder of IV and benefit sharing on commercialisation. The present article discusses these issues, their implications and the action required to achieve the objectives envisaged in the Act, particularly in relation to breeders' rights, researchers' rights and benefit sharing.

Key words: Essentially derived varieties, initial variety, breeders' rights, researchers' rights, benefit sharing

The Protection of Plant Varieties and Farmers' Rights Act, 2001' (PPV&FRA) has been developed in response to Article 27.3(b) of Trade-Related Intellectual Property Rights (TRIPS) agreement under General Agreement on Tariffs and Trade (GATT), and its successor, the World Trade Organization (WTO, 1994). It integrates the rights of breeders', farmers' and communities, and takes care of the concerns for equitable sharing of benefits [1]. The PPV&FRA seeks to provide protection for all plants varieties, including the "essentially derived varieties" (EDVs). As per the definition given in chapter I of the Act- an "EDV in respect of a variety [the initial variety (IV)], shall be said essentially derived from such IV when it-

1. is predominantly derived from such IV, or from a variety that itself is predominantly derived from such IV, whereas, retaining the expression of the essential characteristics

that result from the genotype or combination of genotypes of such IV;

2. is clearly distinguishable from such IV; and
3. conforms (except for the differences which result from the act of derivation) to such IV in the expression of the essential characteristics that results from the genotype or combination of genotypes of such IV."

The concept of essentially derived varieties (EDV)

The concept of essential derivation was introduced by UPOV in 1991 [2] to refine the scope of breeders' rights. The intention of the concept was to confer breeders protection against fraudulent practices in which 'new' varieties are produced from currently protected varieties, sometimes even without a genuine breeding effort. A variety that has passed the standard

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UPOV tests for DUS is therefore, eligible for receiving breeders' rights. Therefore, EDV refers to the situation where the breeder of one variety (the first variety or initial variety) claims that another breeder has developed a new variety (the second or third derived variety) that is distinct for specific feature(s), but predominantly similar and directly related to the first variety (IV) in all important respects.

There is no agreed text, which clearly states what constitute an EDV and how a conclusion can be made on the status of the proposed variety. As per Hunter [3] EDV means, "a new variety" derived from a protected variety, in view of its characteristics, methods and development, it would be considered by a plant breeder a variety to have incorporated essentially the entire genotype of the protected variety plus some new feature(s). Factors to be considered in evaluation are the source of germplasm used and the breeding method employed, including the reasonably expected results of those methods. Under this concept the dependency exists in favour of the protected variety, the IV. The aim of the provisions is to foster the breeding of new and increasingly productive varieties using an IV as a base, and innovative breeding methodologies, including biotechnology. However, most protection systems do not talk about these details and sharing of benefits therefore, further development of the concept is needed, which is important because of such varieties. The protection systems should provide protection, give exemption to the breeders, and have provision of benefit sharing with the developer of IV.

There were a lot of debates at the global level, regarding the definition of EDV and how the protection to this group of variety will be different from a new independently derived variety. The demonstration of essential derivation is the responsibility of the holder of the right of the presumed IV. But, the question is, do the criteria used during the determination of the distinctiveness for the protection of independently derived variety differ from those used for determination of essential derivation? Generally, assessment of independently derived variety is based on distinctiveness, whereas, for assessment

of an EDV is based on the essential derivation, conforming that most genome and the essential characteristics belong to IV, except for the new distinctive characteristic(s) introgressed.

It is believed that different tools may be required for defining essential derivation in relation to trait(s) which is an act of derivation. The genetic similarity to IV can be assessed using both morphological/physiological characteristics and DNA profile, whereas, distinctiveness can be ascertained in addition to phenotypic differences, using trait linked molecular markers. But it may not be of help always, because polyploidy, substitution or addition of chromosomes or chromosome segment, which create such distinctiveness.

Therefore, the definition adopted by PPV&FRA is the most commonly agreed one. However, there is a necessity for clearly defining the starting point of dependence of derivation (*from where it deviates*), in function, genetic distance and technical input. As per the rules and regulations [4], the PPV&FRA envisages registering an EDV distinguishable by at least one characteristic from IV as per DUS criteria, but expressing most essential characteristics of IV (in conformity to IV). In addition, there must be an authorisation for commercialisation of an EDV from the breeder of the IV or the consent of the farmers or group of farmers or community of farmers who have made contribution in the preservation or development of IV (Farmers' variety) to the breeder of the EDV [1: Article 43], complete passport data of the IV from which EDV or its propagating material has been developed and a declaration that the genetic material used has been lawfully acquired as per sub-section 2 of section 28, on mutually agreed terms and conditions. The Act has a provision, to invite claims from any person or group of persons or non-governmental organisation on benefit sharing, that after verification the authority would decide appropriately [1: Article 26]. The principle of equitable benefit sharing has been adopted in conformity of International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).

Registration for a new independently derived

variety representing any variation within a species that satisfies the definition of a variety and fulfil the criteria of distinctiveness, uniformity and stability is easy and straight, but there would be complication in case of EDV, which relates to the scope of the legislation to account for the genetic derivation based on maintenance of most genome and essential characteristics of the IV, used as parent and the method used for incorporation of distinctive feature(s). Therefore, this would need development of appropriate method for assessment of genetic similarity and distinctiveness.

Possibility of misuse of the breeders' exemption

Under Researchers' Rights, a protected variety can be used for research and creation of other varieties [5]. Under these situations, the breeder of a new variety may make full use of the essential features of the IV, without acknowledging and sharing benefits with the breeder of IV. Therefore, to create a balance between protection of rights of initial breeder and freedom for progressive/incremental plant breeding, the concept of EDV has to be understood critically.

Incremental breeding and essential derivation

Incremental breeding leads to development of an unlimited series of new varieties with each subsequent variety being bred relying heavily on the characteristics of the previous variety. As a general rule, easier the access, the more incremental breeding is promoted. Strengthening of the first breeders' rights by extending EDV status to all incrementally bred varieties would promote the fundamentals of the PBR system, with profound benefits for the community of breeders and progress in plant breeding. Breeders' exemption for free access to protected plant varieties for breeding purposes encourages breeders to develop and market new variants (varieties), which favours biodiversity.

Essentially derived varieties derivation

Generally the concept of EDV has been envisaged to account for development of varieties using

new technological approaches. The test of essential derivation from the first variety rests on following criteria:

1. **Technical:** for a variety to be considered essentially derived, it must fulfil the requirement in relation to the IV in retaining the expression of the essential characteristic that is -
 - Conformity to the initial variety in the expression of essential characteristics that result from the genotype of combination of genotypes (a hybrid between EDV with gene of interest and the other parents of the initial variety).
 - It is predominantly derived from the first variety.
 - It does not exhibit differences in any basic features from the first variety except for the trait having clear distinctiveness, and value in cultivation and use, which is an act of derivation.

If any of the requirements is not fulfilled, there is no essential derivation.

2. **Legal aspects:** The claim of the breeder of IV from the breeder of EDV for benefit sharing will hold ground only when -
 - the IV is protected [because it would be based on registration certificate issued under sub-section (8) of section 23, or sub-section (2) of section 24].
 - the IV itself is not an EDV (As practiced by UPOV, due to predominant derivation of essential characteristics from IV, though PPV&FR by definition says that an EDV may be derived from another EDV with incorporation of additional feature, but retaining the essential features of parent IV).
 - Therefore, dependency exists only in case of protected initial (essential) variety (IV) and does not exist on an parent EDV.

Therefore, in practice the concept of dependency is being used mainly to protect the rights of breeder of protected IV.

Essential derivation vs. dependency

Essentially derived and dependency are the two faces of the EDV, introduced by the UPOV convention. Table 1 illustrate the possible situations and their proposed consequences as practiced. But before that let us again clarify the intended meaning of these terms.

Essentially derived

A new variety is deemed to be Essentially Derived, when it contains "virtually" the entire genotype of a variety from which it was developed and thereby "retains the expression of the essential characteristics of the IV. Essentially Derivation is the result of a breeding process. In table 1, each + represents the gene or genes added in essentially derived varieties that were not present in the IV.

Dependency

Dependency refers to for having predominant characters of a protected IV. No dependency exists for an EDV developed from a non-protected variety. Under such situation the clause on benefit sharing under Section 26 will not apply. However, if dependency exists, then the developer of the EDV must seek permission from the owner of the IV prior to the commercialisation as illustrated in table 1.

Thus breeder of IV and EDV as illustrated in table 1 would need-

1. The breeder of an EDV needs to seek permission for its commercialisation from the breeder of an IV from which the EDV was developed only when the dependency of the EDV (for predominant characters) existed on the IV.
2. The dependency exists only when the IV from which the EDV is developed is protected.
3. Dependency ceases after the initial variety has completed its protection period.
4. Dependency as per present rule (practice) cannot exist on an EDV.
5. The breeder of an IV can make a claim for

benefit sharing from the breeder of an EDV, only when IV is protected.

6. If an EDV is developed from a non-protected IV, the breeder of EDV does not need to seek permission for its commercialisation from the breeder of IV.

However, ethically, dependency should extend for an EDV developed from any commercially cultivated common knowledge initial variety.

Measurement of essential derivation for dependency

The essential derivation can be verified based on DUS result in conformity to the agreed threshold. It is similar to calculating minimum genetic distance based on some simply inherited characters. The predominant derivations from the IV using a breeding method may be based on various criteria or a combination thereof, such as, essential characteristics, combining ability, heterosis and molecular identity.

Use of distant coefficient is suggested for measurement of essential derivations to claim dependency, which can help identification of agreed threshold for the reversal of burden of proof. Threshold distance can be calculated based on genetic distance assessed using predominantly morphological or molecular markers. Geneticist and statistician consider that technically it is equally possible to calculate the distance coefficient using morphological markers, but these distances are not always reflective of genetic distance or pedigree relationships. International Seed Federation (ISF) [6] has adopted two thresholds: first threshold below which a variety should be considered as independently derived variety from an IV and a second threshold above which a variety should be considered as essentially derived, except if, the breeder can prove otherwise and that he has started with an independent germplasm.

Between the two thresholds the derivation could be disputable and the breeder of the putative EDV should have to give information on origin of a new variety and produce breeding records. Now ISF has agreed for one threshold above which there would be presumption of

Table 1. Dependency in derivation of essentially derived varieties under different situations

Situation	Detail	Condition	Application of dependency	Permission
I	$A \rightarrow A^+ \rightarrow A^{++} \rightarrow A^{+++}$	<ul style="list-style-type: none"> • A protected • $A^+A^{++}A^{+++}$, EDVs of A with additional features 	$A^+A^{++}A^{+++}$ are dependent on A with conformity of predominance	Developer of $A^+A^{++}A^{+++}$ would need permission for developer of A, IV
II	$B \rightarrow B^+ \rightarrow B^{++} \rightarrow B^{+++}$	<ul style="list-style-type: none"> • B is not protected • $B^+B^{++}B^{+++}$, EDVs of B with additional features 	$B^+B^{++}B^{+++}$ are dependent on B with conformity of predominance	Since B is not protected; EDV developer need no permission
III	$C \rightarrow C^+ \rightarrow C^{++} \rightarrow C^{+++}$	<ul style="list-style-type: none"> • C protected since 2000 • $C^+C^{++}C^{+++}$, EDVs of C with additional features 	$C^+C^{++}C^{+++}$ are dependent on C with conformity of predominance	Since C is protected from 2000, developer of EDV need permission and share benefit for a period of protection of C
IV	$D \rightarrow D^+ \rightarrow D^{++} \rightarrow D^{+++}$	<ul style="list-style-type: none"> • D is protected • D^+ is EDV • $D^{++}D^{+++}$ are EDV, do not have predominance trait of D 	<ul style="list-style-type: none"> • D^+ is dependent on D with conformity of predominance • D^{++} and D^{+++} do not have conformity of predominance to D • D^{++} and D^{+++} have conformity of predominance to D^{++} or D^{+++}, but cannot be dependent on D^{++} or D^{+++} since both are EDV 	<ul style="list-style-type: none"> • D^+ developer need permission for use of IV D • D^{++} and D^{+++} developer need no permission from either D^+ or D^{++} as they are EDV's
V	$E \rightarrow E^+ \rightarrow F \rightarrow F^+$	<ul style="list-style-type: none"> • E is protected • E^+ is EDV of E • F though EDV of E^+, but new • F^+ is EDV of F 	<ul style="list-style-type: none"> • E^+ is dependent on E with conformity of predominance • F now goes beyond EDV, because new • F^+ EDV of F with conformity of predominance 	<ul style="list-style-type: none"> • Developer of E^+ needs permission from E developer • Developer of F do not need permission from E developer as it is new variety • Developer of F^+ need permission from developer of F
VI	$G = H$ (similar to G)	<ul style="list-style-type: none"> • G is protected • H similar to G, but do not appear in parentage 	<ul style="list-style-type: none"> • H is not dependent on G 	<ul style="list-style-type: none"> • H's owner do not need permission from G

IV = Initial variety; EDV = Essentially derived variety; +, ++, +++ Different levels of EDV

{Adopted from: Hunter, R.B. (1999). Essentially derived and dependency, some examples, Intellectual Property Committee, CSTA, Vancouver BC}

derivation, and burden for proof would fall on the breeder of EDV. The threshold will certainly vary from species to species, depending on existing genetic variability within a species and the established breeding procedures.

Possible mode of measurement for discrimination of EDV

Genetic similarity based on molecular markers has been proposed as a tool for differentiation of EDVs. However, scientifically reliable criteria for discrimination of EDVs and independently derived varieties with genetic similarity estimates based on molecular markers are scanty and their implementation as routine into practical breeding is yet to take place. Moreover, UPOV and Indian PPV&FRA include the provisions of distinctness as a matter of phenotypic distinctiveness (DUS characters visible in field with naked eye), though they are an expression of genotype, therefore, molecular markers can only be one basis. However, molecular markers may be used as a supportive tool for establishing similarity and distinctness between IV and EDV. One may agree that substantial portion of DNA does not code for any protein (expression), therefore, it may not be reasonable to hold DNA based evidences to be more vigorous and reliable than applied to morphological evidences [7]. Recently, the genetic distance based on molecular markers, have been found more suitable for genetic conformity between the putative EDVs and their IVs [8] than morphological traits and heterosis, although they are a subject to technical or sampling error. Nevertheless, use of molecular markers as additional tool, besides DUS characters would be preferable course, to establish distinctness and not the genetic similarity (GS). In an attempt to establish scientifically reliable criteria for discrimination of EDV and independently derived varieties with GS estimates based on molecular markers, Hewckenberger *et al.* (2005) opined that standard derivation and overlaps of distribution of GS were smaller with increasing chromosome numbers and length, increasing marker density and uniformity in marker distribution. The degree of polymorphism between parental inbred or donor and recurrent parents influenced the power only if the number of polymorphic markers was low. The factors like

total number of polymorphic markers used, number of markers/chromosomes and distribution of polymorphic markers are critical in deciding power of GS. Availability of markers linked to expressed traits may further enhance the efficacy of marker based procedure.

However, lack of availability of information regarding the total genomic constitution and number of polymorphic markers required to cover the total genome in a number of crops for assessment of the threshold for similarity is a limitation. Therefore, for the time being, it would be more appropriate to make genetic similarity assessment based on morphological features, which are part of the DUS test guidelines as criteria for dependence. For distinctiveness, to conclude about essential derivation, assessment can be made based on phenotypic expression of trait(s) without bothering, whether an essential derivation has been achieved by transfer of specific gene or gene combination to different genetic background in a conversion programme, like placement of cytoplasmic male sterility into different locally adapted or superior cultivars. For example, in case of pigeonpea, CMS ICPL 84023A, in which CMS67A was crossed with ICPL 84023; selfing and backcrossing with recurrent parent ICPL 84023 produced CMS ICPL 84023 in BC5 F1 generation [9]; in cotton, CAK-84635, where *Gossypium aridum* (Rose & Standl.) Skovst. based male sterility has been transferred to AKH 84635 by backcrossing [10]; RCMS-3 using JCMSK2 male sterility source and RGMS-3 converting AC-6 using GMS-1 [11] and in chilli, MS1 and MS3 through backcrossing with Arka Lalit and PMR 64, respectively [12]; in rice, backcross introgression from wild relatives through chromosome segmental substitution resulting in incorporation of resistance to certain biotic and abiotic stresses from *Oryza rufipogon*, *O. longistaminata* and *O. glaberrima*, using molecular markers and backcrossing with recurrent parent [13]; a chromosome substitution (trisomics and monosomic or disomic additional line with alien chromosome) in case of wheat and rice; or a variety derived through somaclonal variation, like BIO-YSR (soma-clonal variant of BEC 286) in case of rapeseed-mustard with resistance to white rust [14] and introgression of

specific gene construct like Bt through genetic transformation or conventional backcrossing in cotton into the putative essentially derived variety. This would have a direct bearing on calculation of genetic distance and would be able to account for all possible type of derivations, achieved through various methods, selection, mutation, translocation, recurrent backcrossing, deletion/substitution, polyploidy, chimera, polyembryony, soma-clonal variation and genetic transformation.

Thus, it would be fair to conclude that for measurement of genetic conformity of EDV to IV, morphological marker approach would be cheaper, as most time, it can be part of DUS testing. A recent study in *Lolium perenne* concluded that the morphological method provided a creditable measure of genetic conformity. Use of molecular marker, AFLP reproduced the same relationships as were evident from examining their morphology and both these results were consistent with the relationships known to exist within the different test groups. Principal components analysis as well as cluster analysis unambiguously associated the IV and the EDV accessions [15, 16]. Nevertheless, the threshold for essential derivation/inclusion of distinctive features at micro/molecular level can be further corroborated using molecular markers. Pusa Basmati-1 is a good example, where EDV status has been established by both morphological and molecular measurement of genetic similarity and distinctness [17]. The introgression of two genes conferring resistance to bacterial blight caused by *Xanthomonas oryzae* pv. *oryzae* into Pusa Basmati-1, used as recurrent parent through phenotypic selection for diseases resistance, agronomic and basmati quality characteristics, and marker-assisted selection for two genes up to BC_1F_3 generation established dependency and derivation, which was corroborated by background analysis using 252 polymorphic amplified fragment length polymorphism (AFLP) markers, which discerned 80.4 to 86.7 per cent recurrent parent alleles (similarity), providing conformity to IV, Pusa Basmati-1, and derivation for resistance to bacterial blight. Further, one may argue on minimum number of backcrosses necessary to qualify the product to be called as

an EDV. In conventional backcrossing at least two backcrosses would be required to recover the average recurrent parent genome to the level of 87.5 per cent on an average. However, as stated above, combining strong phenotypic selection with molecular marker assisted background selection in favour of recurrent parent genome; it may be possible to hasten the recovery of recurrent parent genome even in one backcrossing (selection of individuals having elimination of donor chromosome segments). Therefore, recovery of recurrent genome rather than number of backcross should be the criteria in EDV deduction.

Threshold levels

Thresholds for conformity can be based on the work done in different crops, and respective seed industries have adopted various levels using different types of the molecular markers. For example, based on the work done in maize using RFLP markers based distance, following threshold have been suggested- a) red zone above 90 per cent of similarity; b) orange zone between 90 and 85 per cent similarity and c) green zone below 85 per cent similarity. Recently, a new analysis using microsatellite was completed to agree upon a new threshold accounting for greater variability expressed- a) red zone above 90 per cent of similarity; b) orange zone between 90 and 82 per cent similarity and c) green zone below 82 per cent similarity. In case of hybrid the value for essential derivation can be drawn from the genetic structure deciphered through reverse engineering of parents (construction of parents from hybrid).

Similar threshold levels have been suggested and used in some other crops predominantly using molecular markers. Nevertheless, more scientific work/criteria's are required for the measurement of essential derivations possibly with an evolution of two thresholds into one with greater statistical validations and genealogical data. Though in developed countries, particularly in Europe, the two codes of conduct have already been adapted and have been functioning amicably. Nevertheless, there are cases which have gone to the court, indicating that Standard Operating Protocols for prompt essential derivation will become increasingly important and complex in future.

Registration of EDVs would encourage breeders for corrective breeding in relation to specific traits in existing varieties, which have adaptability genes for the successful expression of their genetic potential and provide benefits to the breeders' of IV (provided they are protected). Therefore, presently, development of thresholds levels for genetic similarity (distance) predominantly based on highly heritable morphological markers or characteristic traits that are key for the description of an initial variety/cultivar would be more appropriate and practical for identification of EDVs. Nevertheless, whatever methodology is followed, a code of conduct on general threshold can be derived as is being followed by the French maize seed industry inferring that above threshold with 90 per cent similarity, the variety should be considered as EDV without further discussion; between 90 and 82 per cent there is a possibility of essential derivations which parties can negotiate, whereas, below 82 per cent it would not be a case of essential derivations.

The concept of derivation and dependence with quantitative definitions will prevent cosmetic breeding changes or plagiarism (development of EDV with traits of no commercial value), which sometime could allow creation of distinct varieties in one sense, but beyond the broad concept of breeders, farmers and that of biological diversity will impact the breeders work and claim for essential derivations. Some breeding methods associated with creation of higher degree of essential derivations are -

- Simple selection from existing variety for novelty, for example a pure line selected from a landrace (e.g., Type 3 from Dehradun Basmati rice).
- Natural or induced mutation (Sarbat Sonora wheat from Sonora 64).
- Repeated backcrossing and recurrent selection (Improved Pusa Basmati-1 from Pusa Basmati).
- Genetic transformation using gene construct.
- Somaclonal variation (Pusa Jai Kisan from Varuna).

Burden of proof

In case of a dispute, the initial burden of proof lies on the owner of IV to prove essential derivations and then claim dependency. This can be relaxed in case the owner gives reasonable evidence on essential derivations as *prima-facy-proof* such as-

- Strong phenotypic similarity with IV.
- Strong genetic similarity.
- Only small differences for some simply inherited character.

If the owner of the IV fulfilled the above requirements then the second breeder would have to prove that there is no predominant derivation. In cases where a variety has a few essential characters different from IV (not providing benefit in terms of total derivation) it should be considered EDV only. For example, if a new apple variety developed from an existing variety differs from existing variety only in cosmetic features, such as leaf colour or shape, but produces fruit that is identical in shape, colour and taste to that of existing variety, it may be considered an essentially derived variety only. In such cases, the breeder of IV should be entitled for an equitable remuneration as per the provision of Act, under rules in chapter IV clause 41 c and as per the clause 43 on determination of benefit sharing under section 26. This means distinctiveness originating from the act of derivation, for an essential character of non-commercial value should not be taken into account for establishing the status of independent variety to a putative EDV. If this does not happen the very purpose of bringing in EDV clause is defeated, as it primarily aims at protecting the rights of IV's breeder.

Implications

As essential derivations and then claim for dependency will be applicable only on protected IVs, therefore, it is required that varieties that have been released and notified under the appropriate law (In India section 54 of Seeds Act 1966) are yet to complete period of protection from the date of notification (15 years) must be

protected, as the dependency does not exist on non-protected variety. It would be in the interest of the breeders/organisation of such extant varieties to get them protected in order to have the mechanism of benefit sharing enabled. Same would be applicable to farmers' varieties selected and maintained over generations with specific traits. Some social organisation has to come forward in this regard for obtaining ownership rights to farmers'/communities. These varieties are likely to be used for development of EDV by both public and private sector breeders.

Ethically, principle of essential derivation and provision of benefit sharing need be extended to all common knowledge commercial varieties and a mechanism for protecting the right of breeder of an IV, used to develop an EDV for which no protection has been sought, must be developed. The essential characters have been given greater importance for claiming dependency, deviation in which may help in claiming an EDV to be an independently derived variety; therefore, greater weightage should be given to genetic similarity.

No dependency exist if an EDV is developed from another EDV (as per practice followed by UPOV), this provision has serious implications in terms protecting the interest of the breeder of an EDV, where the commercial benefit is accrued from the character of EDV used in further improvement/incremental breeding are significant. For example, a breeder of A++ exploiting the benefits of a trait, say 'Bt' added by the breeder of A+, involved in development of A++ without benefit sharing. Therefore, it is necessary protecting the interest of the breeder of an EDV as per the definition in the PPV&FR Act, can be developed from a variety that itself is EDV (predominantly derived from an initial variety). Therefore, a suitable mechanism/practice for proportionate benefit sharing need to be developed to protect the interest of the breeder who's EDV has been used for developing another EDV. Burden of proof should not lie on the breeder of IV only, but should be equally shared by the breeder of EDV for not being dependent on IV with hard data and breeding records.

The breeders would have to pay greater attention to the results of their breeding efforts, when working with a protected variety in the framework of breeders' exemption. If a breeding effort results in a product, which is above the broad definitions generally used to define a new independently derived variety, it is an EDV. An authorisation of the breeder of the IV is required for commercialisation. Commercialisation should be granted on conformity of threshold of essential derivations, as discussed above or as per the agreement or on case to case basis. In the entire situation the threshold level has to be defined in advance for a breeder to know its limits in relation to-

1. Range of phenotypic, physiological and molecular variability of varieties present in the seed chain.
2. Phenotypic, physiological and molecular profile of the genetic material and experimental variety with breeding history (the breeder will need to employ suitable methods for assessing such profiles).
3. Commercial value of added/distinctive traits (for benefit sharing).
4. Maintaining breeding records.

Data keeping of above information will help the breeders to maintain threshold in conformity to the derivation as per the accepted guidelines and seek professional/legal advice for the registration of a variety.

It is required that in important crops a multivariate cluster analysis is performed on reference/notified varieties for scaling of GS and identify a cut-off point, or threshold in order of similarities (say 90%), beyond which variety pairs will classify as being suspected as new or essentially derived. This may be further supported with some example of GS levels between an IV and EDV in respective crops. The level of genetic variation found in a crop may be a consideration for establishment of standards. Similarly, a threshold for potential derivation is to be set using the same similarity matrix.

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